

## REMARKS

Reconsideration of this application, as amended, is respectfully requested. In light of the amendments made above and the comments which follow, it is believed that all other issues are removed and that this application is in condition for passage to allowance.

### *Status of All of the Claims*

Upon entry of this submission, claims 27-67 will be pending and under consideration. New claims 45-67 have been added. Support for these amendments is discussed herein below.

### *Claim Rejections – 35 U.S.C. § 102*

Claims 27, 29, 31-33, 38, 40, 42-44 stand rejected under 35 U.S.C. §102(e) as being anticipated by Babbs et al., U.S. Patent 6,475,232. This rejection is traversed.

Applicants disagree with the Examiner's interpretation of the phrase "so as to cause a full occlusion and full blockage of the vascular vessel" in claims 27 and 32. Respectfully, Applicants assert that the Examiner's interpretation of this phrase is unreasonable, and that the Examiner has failed to give this phrase its ordinary and customary meaning.

Examiners have a duty to give claim terms their ordinary and customary meaning consistent with the specification. The ordinary and customary meaning of a claim term is that which the skilled artisan would have attributed to that term at the time of the invention. Despite the importance of the skilled person in this analysis, the Examiner has produced no real evidence to show that the skilled artisan would have agreed with the Examiner's interpretation of the phrase "so as to cause a full occlusion and full blockage of the vascular vessel" in claims 27 and

32. On the other hand, Applicants have produced evidence that directly contradicts the Examiner's interpretations, and they produce additional contradictory evidence below.

As previously stated, a common definition for the term "occlude" is "to close, obstruct, or prevent the passage" (See, e.g., previously submitted definition from MedicineNet.com). This definition is compatible with Applicants use of the term in the application, and is compatible with how those skilled in the vascular occlusion art would have interpreted this term at the time of the invention. To further illustrate this point, Applicants ask the Examiner to please refer to column 5, lines 19-20 of U.S. Patent No. 6,660,034 to Mandrusov et al. There it states:

"Occlusion" is defined as the total or partial obstruction of blood flow through a vessel.

Thus, to those skilled in the art of vascular occlusion, the phrase "to fully occlude a vessel"

---

means to fully close, to fully obstruct, or to fully prevent the passage of blood flow through the vessel. Applicants re-emphasize that claims 27 and 32 require full occlusion of the vessel.

The Babbs device clearly does not fully occlude the vessel. That is, it does not fully prevent the passage of blood flow through the vessel. In fact, the Examiner has pointed out on multiple occasions that the deployed stent devices taught by Babbs are designed to keep the blood vessel lumen open, thereby permitting blood to flow through the lumen. Thus, Applicants simply do not see how one can reasonably conclude that the ordinarily skilled person in the medical field would understand that the Babbs device, which is designed to hold the vessel open to allow blood to flow through the vessel, would also be effective to fully close the vessel to prevent blood from flowing through the vessel. These two outcomes contradict one another, and thus, Babbs cannot possibly anticipate the subject matter of claims 27 and 32 under any

reasonable interpretation of the phrase “so as to cause a full occlusion and full blockage of the vascular vessel.” For at least these reasons, Babbs does not anticipate the subject matter of any of claims 27, 29, 31-33, 38, 40, 42-44. Withdrawal of these rejections is therefore solicited.

***Claim Rejections – 35 U.S.C. § 103***

Claims 37, 39 and 41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Babbs et al. U.S. Patent 6,475,232 in view of Li, U.S. Patent 5,512,291. For at least the reasons stated above, the Babbs et al. reference does not render any of the pending claims obvious. Moreover, the Li reference does not add anything to overcome the shortfalls of the Babbs reference. In fact, to do so would completely undermine the function of the Babbs structure, which is a strong determinant against this or any other combination including Babbs. Therefore, withdrawal of this rejection is solicited.

---

New claims 45-67 are patentable and are supported by the original disclosure. Thus, no new matter has been added by way of these amendments. As to patentability relative to the cited references, each of these new claims requires the inserted embolization device to fill the blood vessel or aneurysm, cause embolus, and in the case of a blood vessel, to fully occlude. This is a dramatic contrast to the features of a stent device that holds vessels open, as discussed in Babbs et al. Further, support for claims 45-67 includes the following.

There is much discussion in the application about preparing and using embolization devices that are free from any metallic component, as well as about devices that include a metallic component. Implanting a device that is free from any metallic component so as to leave behind an all natural blockage is disclosed, for example, in paragraph [0100].

Using a thrombogenic collagenous biomaterial that is harvested from animal tissue and contains at least one biotropic agent selected from a proteoglycan, a growth factor, a glycoprotein, and a glycosaminoglycan is disclosed, for example, in paragraph [0013]. Biomaterial sheets are disclosed, for example, in paragraph [0086].

Delivering an embolization device to a blood vessel or an aneurysm is discussed throughout the application. Delivery via a delivery catheter is disclosed, for example, in paragraphs [0089] and [0095]. Filling a blood vessel or aneurysm is disclosed, for example, in paragraph [0085] and original claim 25. Causing formation of an embolus is disclosed throughout the specification including, for example, in the Abstract and paragraph [0086]. Using thrombogenic materials to promote the formation of thrombus is disclosed throughout the specification. Causing a full occlusion is disclosed, for example, in paragraph [0086].

A thrombogenic collagenous biomaterial being biodegradable and promoting a healing response in the patient so as to result in an all natural blockage of a blood vessel is disclosed, for example, in paragraphs [0012], [0068] and [0100].

A thrombogenic collagenous biomaterial comprising submucosa, pericardium, basement membrane, or amniotic membrane is disclosed, for example, in paragraph [0013].

A thrombogenic collagenous biomaterial sheet or a thrombogenic component promoting a healing response in the patient so as to result in tissue ingrowth into an area of the blood vessel into which the embolization device is delivered is disclosed, for example, in paragraphs [0011] and [0012].

A thrombogenic component prepared from a thrombogenic collagenous biomaterial sheet, wherein the component is a comminuted component, a branched component, a helical

component, a spherical component, a cubic component, or a cylindrical component is disclosed, for example, in paragraph [0086].

Incorporating a metallic backbone to which a collagenous biomaterial is attached is disclosed, for example, in paragraph [0100].

A thrombogenic collagenous biomaterial also comprising a radiopaque substance is disclosed, for example, in paragraphs [0013] and [0086].

Additional support for claims 45-67 can be found throughout the specification and drawings.

### **Conclusion**

In view of the foregoing, reconsideration and withdrawal of all outstanding rejections, and passage of this application to allowance, are solicited.

### **Request for Interview**

In the event that the Examiner finds any reason that the application cannot be allowed in its present form, the Applicant wishes to conduct an interview with the Examiner prior to any next Office Action in order to provide an opportunity for coming to agreement upon allowable claims. To arrange the interview, the Examiner should call the undersigned attorney at the telephone number given.

Respectfully submitted,

By   
\_\_\_\_\_  
Timothy B. Paul, Reg. No. 51203  
Woodard, Emhardt, Moriarty, McNett & Henry LLP  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
Telephone: (317) 634-3456 Fax: (317) 637-7561  
Email: tpaul@uspatent.com